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INTRODUCTION

The purpose of this multi-site study is to conduct a randomized controlled trial of the Caring Letters intervention to determine if the intervention is effective in preventing suicide and suicidal behaviors among Service Members and Veterans. The “caring letters” concept was originally developed and evaluated by Jerome Motto and colleagues in the 1970’s (1). In Motto’s trial, civilian psychiatric inpatients were sent caring letters following discharge (initially monthly, decreasing to quarterly) for five years. Compared to a control group (usual care) with no further contact, the Caring Letters group had a significantly lower suicide rate for the first two years of the trial. These “caring letters” are one of the only suicide prevention interventions to reduce suicide mortality in a randomized controlled trial (2). Despite the initial promising results of the original Caring Letters RCT, there have been no published replications of the original intervention or tests of the intervention among military personnel or veterans. This study will fill an important gap in the evidence base for the Caring Letter intervention and is timely given the steady increase of military suicide in recent years.

BODY

The team submitted continuing review for Madigan Army Medical Center, Tripler Army Medical Center, Landstuhl Regional Medical Center and Naval Medical Center San Diego for review and approval on 25 June 2014. We have received IRB approval for Continuing Review from 25 June 2014 – 24 June 2015. Palo Alto VA received IRB continuing review on 22 July 2014. They are approved from 22 July 2014 – 22 July 2015. HRPO acknowledgement of continuing review was received as well. The team submitted continuing review for VAWNYHS and received IRB continuing review from 23 October 2014 through 23 October 2015. Continuing review was submitted to HRPO for MAMC, TAMC, and NMCSD on 17 July 2014 and on 31 July 2014 continuing review was submitted to HRPO for LRMC. Continuing review was submitted for VAPA on 16 September 2014.

Amendments:

MAMC
03 March 2014 approval to add Tina Lee, MD as the PI at Palo Alto VA, and remove Jennifer Hoblyn.
26 June 2014: Approval to change lead PI at MAMC from Dr. David Luxton to Dr. Nancy Skopp
18 August 2014: Approval of addition of LTC Judy Kovell, MD as PI at Tripler Army Medical Center and removal of Dr. Helenna Nakama.
17 February 2015: Approval to revise final follow-up data collection process.

LRMC
03 March 2014: Initial revision of final follow-up process.
07 April 2014: Updating contact information for PI and HIPAA privacy officer.
11 July 2014: Addition of Heather Cosimo as Research Coordinator.
13 January 2015: Addition of Martha Munoz and removal of Sara Lauterwasser and Heather Cosimo.
25 February 2015: Approval of the final follow-up data collection process.

TAMC
27 March 2014: Remove Jill Stack as coordinator and addition of Nina Bermudez as coordinator and initial revision of final follow-up.
11 July 2014: Addition of collaborating staff Jessica Stewart.
20 August 2014: Change site PI from Helenna Nakama to Judy Kovell.
28 October 2014: MFR reviewed regarding failure to report local SAE and corrective action plan. This was accepted noting no subjects were harmed or placed at risk.
13 November 2014: TAMC IRB reviewed SAE noted in regards to the failure to report
02 December 2014: TAMC review of SAE dated 29 October 2014.
15 December 2014: Addition of collaborating staff Christina Parkinson.
03 March 2015: Revision to the final follow-up.

NMCSD
07 March 2014: Initial revision of the final follow-up.
18 November 2014: Local requirements to add medical monitor CDR Salee Oboza.
03 March 2015: Revision to the final follow-up.

VAWNYHS
02 March 2015: Revision to the final follow-up

Submission of SAE: Submission of adverse events: One participant died by suicide and this was reported to the MAMC IRB on 22 April 2014. This participant was enrolled at the TAMC site. At TAMC, one SAE was reported and acknowledged on 12 November 2014. This was a suicide not related to the study.
At VAPA seven SAEs were reported. Three of these deaths were related to medical illness, not the study. Three deaths were completed suicides, not related to the study. One death was not considered a suicide but was classified as a death due to a mixed combination of drugs.

On 30 September 2014, Dr. Victoria Garshnek, Human Protection Administrator (HPA), TAMC, contacted MAMC RRS and pointed out that a Reportable Event that had been submitted to MAMC IRB (IRB of record) from 24 April 2014 had not been submitted to the TAMC IRBnet portal for review per reporting guidelines in the reciprocal IRB agreement between WRMC/Madigan and TAMC. The Reportable Event package was submitted on 30 September 2014 to TAMC. This failure to report was an isolated incident and after review of all previous submissions found to be the only instance. A MFR was written to the IO at WRMC. This was submitted to the MAMC IRB and the correction action plan was accepted on 28 October 2014.

Deviations: A deviation at the TAMC site was reported to the MAMC IRB on 31 July 2014 and acknowledged. A duplication of enrollment occurred at the site. A change in enrollment process was implemented so that this does not occur in the future.

Presentations: Dr. Luxton attended and presented the Caring Letters Project at the IPR held in Ft. Detrick on 14/15 May 2014. Dr. Luxton presented study overview/progress at the American Psychological Association Annual Convention, Washington DC in August 2014.

Internal Audits: VAPA and NMCSD both completed audits by the research compliance office and there were no findings at either location.

Recruitment ended on 31 December 2014 in order to allow for the two year follow-up and close-out procedures of the grant. A total of 1319 patients have been enrolled into the study at all sites, (MAMC, Palo Alto VA, LMRC, VAWNYHS, TAMC and NMCSD).

Final Data Collection: Final outcomes assessments have begun at all sites. Anticipated final follow-up data collection date is 31 December 2016. The team plans to request a one year NCE (Feb 2016 – Feb 2017).

Challenges

TAMC coordinator began employment on 10 March 2014 and completed training. The LRMC coordinator resigned 10 July 2014. Recruitment, interviewing and hiring of a coordinator was completed. The new LRMC coordinator began 23 June 2014 and training is completed. A Project Manager was hired (at main site) and began on 07 July 2014 at a 5% rate of effort. Training is completed and percentage of effort increased on 28 February 2015 to 100%. Replacement LRMC coordinator resign position effective 07 November 2014. Recruitment, interviewing and hiring of a coordinator was completed. The new LRMC coordinator began 08 December 2014 and training is completed. This position was decreased to a 50% effort. The MAMC coordinator resigned on 12 December 2014. Recruitment, interviewing and hiring of a coordinator was completed. The new MAMC coordinator began 08 December 2014 and training is process while we await CAC card.
During the conduct of completion of final follow-ups it was determined that the rate of completion was low and to increase the collection of all final measures an amendment was submitted and approved for coordinators to complete all measures via phone. As this amendment was recently approved it's too soon to tell if this amendment has helped increase the rate of completion for final follow-ups.

KEY RESEARCH ACCOMPLISHMENTS

Administrative and Logistical Matters

1. Personnel
    a. Recruitment, interviewing and hiring of research coordinators at all sites has been completed. The grant PI, David Luxton, PhD, has requested a reduction in his percentage of effort from 25% to 10%. This was approved on 21 November 2014.
2. Equipment
    a. None required at this time.
3. Materials, supplies and consumables
    a. Materials and required supplies continue to be coordinated in anticipation for data collection and future archive and close-out procedures.
4. Institutional Review Board (IRB)

a. MAMC IRB continuing review approved on 26 June 2013..(Continuing review until 25 June 2014) (MAMC, TAMC, LRMC and NMCSD)

b. VA Palo Alto continuing review approved until 23 July 2014.

c. VA Western New York Buffalo approved until 23 October 2014.

d. HRPO IRB initial approval for all sites has been received. Continuing review acknowledgement for sites has been received.

REPORTABLE OUTCOMES

None

CONCLUSION

None

REFERENCES

1. Motto JA, Bostrom AG. A randomized controlled trial of postcrisis suicide prevention. *Psychiatr Serv*. 2001; 52(6):828-833.

2. Luxton, D. D., June, J. D. & Comtois, K. A. (2013). Can Post-Discharge Follow-up Contacts Prevent Suicide and Suicide Behavior?: A Review of the Evidence. *Crisis: The Journal of Crisis Intervention and Suicide Prevention. 34,* 32-41.

APPENDICIES

None